

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

----- HADLEY SCOTT SMITH, : : Plaintiff, : : v. : : C.R. BARD, INC.; DAVOL INC., : : Defendants. : ----- 	X : : : : : : : : : : X
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Civil Action No.: 07-cv-7934 (LLS)

**ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS C.R. BARD,
INC. AND DAVOL INC.**

Defendants C.R. Bard, Inc. (“Bard”) and Davol Inc. (“Davol”), (collectively “Defendants”) by and through counsel, answer the Plaintiff’s Complaint (“Complaint”) as follows:

NATURE OF THE CASE

1. Paragraph 1 of the Complaint contains allegations that are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

PARTIES

2. Paragraph 2 of the Complaint contains allegations regarding parties other than Defendants to which no response is required. To the extent that a response is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 2 of the Complaint and therefore deny the same.

3. These allegations are not directed at Bard, and to the extent they are, Bard denies them. Davol Inc. (“Davol”) admits that it is a subsidiary of C.R. Bard, Inc. (“Bard”) organized under the laws of the State of Delaware with its principal place of

business at 100 Sockanosset Crossroad, Cranston, Rhode Island, where its hernia surgical repair business is based. Davol further admits that it has conducted limited manufacturing of the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information.

4. Bard admits that it is organized under the laws of the State of New Jersey and that Davol is its subsidiary. Bard denies the remaining allegations.

5. The allegations in Paragraph 5 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

6. The allegations in Paragraph 6 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 6 and therefore deny the allegations.

FACTUAL ALLEGATIONS

7. These allegations are not directed toward Bard, and to the extent they are, Bard denies them. Davol admits that it designed, distributed, and manufactured the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. As to the remaining allegations contained in Paragraph 7 of the Complaint, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 7 of the Complaint and therefore deny the same.

8. These allegations are not directed toward Bard, and to the extent they are, Bard denies them. Davol admits that it manufactured the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling

information. As to the remaining allegations contained in Paragraph 8 of the complaint, Defendants do not know what is meant by "delivery" beyond the meaning of "distributed", which has been admitted, or lack sufficient knowledge or information to form a belief as to the truth of the allegations. Defendants accordingly deny the remaining allegations.

9. Defendants admit that Davol submitted a 510k Application on October 23, 2000. On January 22, 2001, the federal Food and Drug Administration approved Davol's Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information.

10. Davol admits that it distributed and sold the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. Davol does not know what is meant by "marketing" or "tested" beyond the meaning of "designed," "manufactured," or "distributed," which have been admitted. Davol accordingly denies these allegations. Bard denies these allegations.

11. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint and therefore deny the same.

12. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint and therefore deny the same.

13. Defendants admit that the federal Food and Drug Administration characterizes a "Class I" recall as potentially life threatening or posing a potential for serious bodily harm.

14. Defendants admit that a limited voluntary recall of certain larger-sized Composix® Kugel® Hernia Patches took place due to a potential for PET recoil ring

breaking. Davol further admits that it has received reports of ring migration, intestinal fistulae, bowel perforation, and death. As to the remaining allegation contained in Paragraph 14, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in the paragraph, and therefore Defendants deny the allegations.

15. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 15 of the Complaint and therefore deny the same.

16. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint and therefore deny the same.

17. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 17 of the Complaint and therefore deny the same.

18. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 18 of the Complaint and therefore deny the same.

19. Defendants deny the allegations contained in Paragraph 19 of the Complaint.

20. Defendants deny the allegations contained in Paragraph 20 of the Complaint.

21. Defendants deny the allegations contained in Paragraph 21 of the Complaint.

22. Defendants deny the allegations contained in Paragraph 22 of the Complaint.

FRAUDULENT CONCEALMENT

23. The allegations in Paragraph 23 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

24. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 24 of the Complaint and therefore deny the same.

25. The allegations in Paragraph 25 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

CLAIMS FOR RELIEF
Count I-Negligence

26. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

27. The allegations in Paragraph 27 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

28. The allegations in Paragraph 28 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

29. The allegations in Paragraph 29 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

30. The allegations in Paragraph 30 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

31. The allegations in Paragraph 31 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

32. The allegations in Paragraph 32 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

33. The allegations in Paragraph 33 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

34. The allegations in Paragraph 34 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

35. The allegations in Paragraph 35 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

Count II-Strict Liability: Failure to Warn

36. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

37. Davol admits that it designed, manufactured, and sold the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. Bard denies these allegations. As to the remaining allegations contained in Paragraph 37 of the complaint, Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in the paragraph therefore deny all remaining allegations.

38. The allegations in Paragraph 38 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

39. The allegations in Paragraph 39 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

40. The allegations in Paragraph 40 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

41. The allegations in Paragraph 41 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

42. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 42 of the Complaint and therefore deny the same.

43. The allegations in Paragraph 43 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

Count III-Strict Liability: Design Defect

44. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

45. Davol admits that it designed, manufactured, distributed and sold the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information. As to the remaining allegations contained in Paragraph 45 of the complaint, Defendants do not know what is meant by "assembled" or "conveyed" beyond the meanings of "manufactured" and "distributed" which have been addressed above. Davol accordingly denies the remaining allegations. Bard denies these allegations.

46. The allegations in Paragraph 46 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

47. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 47 of the Complaint and therefore deny the same.

48. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 48 of the Complaint and therefore deny the same.

49. The allegations in Paragraph 49 and its subparts (i) through (x) are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

50. The allegations in Paragraph 50 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

Count IV-Breach of Implied Warranty

51. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

52. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 52 of the Complaint and therefore deny the same. As to the remaining allegations in Paragraph 52, they are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

53. The allegations in Paragraph 53 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

54. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 54 of the Complaint and therefore deny the same.

55. The allegations in Paragraph 55 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

56. The allegations in Paragraph 56 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

Count V-Breach of Express Warranty

57. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

58. The allegations in Paragraph 58 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

59. The allegations in Paragraph 59 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

60. The allegations in Paragraph 60 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

61. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 61 of the Complaint and therefore deny the same.

62. Defendants lack sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 62 of the Complaint and therefore deny the same.

63. The allegations in Paragraph 63 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

Count VI-Fraud

64. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

65. The allegations in Paragraph 65 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

66. The allegations in Paragraph 66 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

67. The allegations in Paragraph 67 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

68. The allegations in Paragraph 68 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

69. The allegations in Paragraph 69 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

70. The allegations in Paragraph 70 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

71. The allegations in Paragraph 71 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

72. The allegations in Paragraph 72 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

Count VII-Negligent Misrepresentation and Omission

73. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

74. The allegations in Paragraph 74 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

75. The allegations in Paragraph 75 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

76. The allegations in this Paragraph are directed toward Pfizer who is not a party to this case. To the extent these allegations are directed toward Bard or Davol, Defendants state the allegations in Paragraph 76 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

77. The allegations in Paragraph 77 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

78. The allegations in Paragraph 78 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

79. The allegations in Paragraph 79 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

Count VIII-Violation of Gen. Bus. L. § 349

80. Defendants incorporate by reference their responses to each and every allegation contained in foregoing paragraphs as though fully set forth herein.

81. The allegations in Paragraph 81 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

82. The allegations in Paragraph 82 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

83. The allegations in Paragraph 83 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

84. Defendants admit that Davol designed, manufactured, distributed, and sold the Composix® Kugel® Hernia Patch for use by prescribing physicians in accordance with its accompanying labeling information in the State of New York. Davol does not know what is meant by “market[ed],” “advertis[ed],” or “promot[ed]” beyond the meanings of distributed and sold which have already been admitted. Davol accordingly denies the allegations. Bard denies the allegations.

85. The allegations in Paragraph 85 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

86. The allegations in Paragraph 86 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

87. The allegations in Paragraph 87 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

88. The allegations in Paragraph 88 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

89. The allegations in Paragraph 89 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

90. The allegations in Paragraph 90 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

91. The allegations in Paragraph 91 are conclusions of law, and no answer is required. To the extent an answer is required, Defendants deny the allegations.

92. Defendants deny each and every allegation of each and every paragraph contained in the Complaint not expressly admitted.

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against Defendants upon which relief can be granted.

2. The Plaintiff's Complaint should be dismissed for lack of proper venue.

3. The doctrines contained in Restatement (Second) of Torts § 402A, Comment k, bar Plaintiff's claims against Defendants in whole or in part

4. The doctrines contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar Plaintiff's claims against Defendants in whole or in part.

5. The doctrine of spoliation and the failure to properly preserve evidence necessary to the determination of the alleged claims bars them.

6. Applicable statutes of limitations, statute of repose, and the doctrine of laches bar Plaintiff's claims in whole or in part.

7. Plaintiff's, or his agents', including his physicians', misuse or abnormal use of the product or failure to follow instructions bar the Plaintiff's claims in whole or in part.

8. If Plaintiff used a product sold by Defendants, then Plaintiff's claims are barred, in whole or in part, because Plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

9. Any alleged negligent or culpable conduct of Defendants, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of Plaintiff's alleged injuries.

10. If Plaintiff sustained any damages or injuries, then such damages and injuries were caused or contributed to by the acts, omissions or fault of Plaintiff, including contributory negligence, contributory fault, comparative fault; assumption of the risk, or failure to mitigate damages.

11. If Plaintiff used a product sold by Defendants, Plaintiff used the product for off-label purposes, which bars the Plaintiff's claims.

12. The learned intermediary doctrine bars Plaintiff's claims.

13. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

14. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

15. Plaintiff's claims are preempted, in whole or in part, by applicable federal law.

16. Plaintiff's claims are barred, in whole or in part, because Plaintiff's injuries, if any, were the result of conduct of Plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to Plaintiff's pre-existing medical conditions.

17. If Plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which Defendants are neither liable nor responsible or resulted from diseases and/or causes that are not related or connected with any product sold, distributed, or manufactured by Defendants. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of Plaintiff's alleged injury or damages.

18. Defendants state that if Plaintiff sustained any damages or injuries, which is specifically denied, and such damages or injuries were caused by the acts, omissions or fault of Plaintiff or others, for whose conduct Defendants are not responsible; accordingly, Defendants are entitled to an assessment of the relative degree of fault for all such persons and entities.

19. Plaintiff's claims are barred, in whole or in part, because Plaintiff's alleged injuries, if caused by the Composix® Kugel® Hernia Patch, which is denied, were the result of Plaintiff's own idiosyncratic reactions.

20. Plaintiff failed to mitigate, which limits Plaintiff's damages, if any, in whole or in part.

21. Defendants have no legal relationship or privity with Plaintiff and owe no duty to Plaintiff by which liability could be attributed to it.

22. Defendants made no warranties of any kind, express or implied, or any representations of any nature whatsoever to Plaintiff. If any such warranties were made, whether express or implied, which Defendants specifically deny, then Plaintiff failed to give notice of any breach thereof. Moreover, Defendants effectively and fully disclaimed any warranty, express or implied, in the sale of any product for which they are responsible in this matter.

23. Plaintiff's causes of action are barred in whole or in part by Plaintiff's own comparative negligence.

24. Plaintiff's recovery, if any, shall be reduced by those payments that Plaintiff received from collateral sources.

25. If Plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by Defendants' product.

26. At the time the product at issue, the Composix® Kugel® Hernia Patch, left the custody and control of Defendants, there was no defect in said product that either caused or contributed to any injuries or damages that Plaintiff may have suffered, if any.

27. The applicable state and federal law, including *State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003), bars Plaintiff's alleged claims for punitive or exemplary damages. Permitting recovery of punitive or exemplary damages in this case would violate Defendants' rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution, and related provisions of the

United States Constitution, as well as the applicable due process guarantees embodied in the New York Constitution.

28. To the extent that the applicable state law permits the jury and Courts to measure punitive or exemplary damages by the net worth or financial status of Defendants and imposes greater punishment on defendants with greater net worth, such an award would be unconstitutional because it permits arbitrary punishment, allows bias and prejudice to infect the verdict, and allows dissimilar treatment of similarly situated defendants, all in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the similar provisions of the New York Constitution.

29. To the extent Plaintiff's Complaint seeks punitive damages, such claims are barred because Plaintiff has failed to allege conduct warranting the imposition of punitive damages under New York and/or other applicable laws.

30. To the extent Plaintiff's Complaint seeks punitive damages, applicable federal law preempts any such claim, in whole or in part.

31. Plaintiff's claims are, in whole or in part, subject to adjudication under the laws of states or jurisdictions other than New York.

32. Defendants hereby give notice that they intend to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves their right to amend this Answer to assert such defenses.

WHEREFORE, Defendants C.R. Bard, Inc. and Davol Inc. demand judgment in their favor and against Plaintiff, dismissing Plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY TRIAL DEMAND

PLEASE TAKE NOTICE that answering Defendants hereby demand a trial by jury as to all issues.

Dated: New York, New York
September 11, 2007

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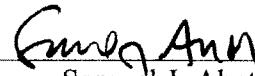
Attorneys for Defendants
C.R. BARD, INC. and DAVOL INC.

CERTIFICATE OF SERVICE

I hereby certify that on September 11, 2007, a copy of the foregoing Answer and Affirmative Defenses has been made upon the following in the manner listed below:

David Buchanan
One Williams Street
New York, NY 10004

via first-class, postage prepaid, mail



Samuel J. Abate, Jr. (SA 0915)